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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,101	10/02/2003	Maria Paola Belloni Regazzo	38170/GM/ch	1685
7590 02/07/2005 MODIANO & ASSOCIATI Via Meravigli, 16 MILANO, 20123 ITALY			EXAMINER MCCORMICK EWOLDT, SUSAN BETH	
			ART UNIT 1654	PAPER NUMBER

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/676,101

Applicant(s)

BELLONI REGAZZO, MARIA
PAOLA

Examiner

Susan B. McCormick-Ewoldt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) 8, 9 and 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10 and 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date November 26, 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's species election of essential oils from leaves of *P. lentiscus* in the reply filed on December 3, 2004 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8, 9 are 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 3, 2004.

Claims Pending

Claims 1-7, 10 and 15-21 will be examined on the merits.

Claim Objections

Claims 2 and 5 are objected to because of the following informalities: claim 2 has two periods and claim 5 has no period at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claim 1-7, 10 and 15-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating or preventing cancer and does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is "undue," not "experimentation." " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicted on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is

needed is not a single, simple factual considerations.” (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case, are discussed below.

Inventions targeted for treating or preventing cancer bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is high for such inventions because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because as the state of the art stands, there is no “prevention” or “cure” for cancer and cancer treatments are rare. Thus, claims to treatment and especially prevention may be unbelievable in the absence of strong supporting evidence. It is noted that the instant claim encompasses cancer that can be prevented or reduced, and yet the instant specification provides no working examples and no guidance that would permit the skilled artisan to use the invention.

In the instant case, Applicant has disclosed that the claimed composition is useful in treating cancer. The claims specifically disclose treating breast adenocarcinoma, colon adenocarcinoma and ovary adenocarcinoma in a human, while in the specification, Applicant provides no working examples and no guidance that would permit the skilled artisan to practice the invention commensurate with the *scope* of the instant claim. Also, in addition, the claim also encompass using *Pistacia lentiscus* oil to treat cancer which is clearly beyond the scope of the instantly disclosed/claimed invention.

Since there are no working examples, then one must consider the guidance provided by the instant specification and the prior art of record. As stated *supra*, the state of the art is unpredictable as it reflects that there is no cure of cancer. Although the present claim recites

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“prevention,” prevention is deemed to be a “cure” since prevention of a disease is interpreted to mean that the disease will entirely cease to manifest after administration of the composition. Further, with regard to cancer treatment, Bally *et al.* (US 5,595,756) stated, “Despite enormous investments of financial and human resources, no cure exists for a variety of diseases. For example, cancer remains one of the major causes of death. A number of bioactive agents have been found, to varying degrees, to be effective against tumor cells. However, the clinical use of such antitumor agents has been highly compromised because of treatment-limiting toxicities” (col. 1, lines 17-24). Applicant has not demonstrated inhibition or treatment of cancer *in-vitro* or even in a mouse/rat model in order to provide some reasonable nexus between *Pistacia lentiscus* oil and cancer treatment and/or prevention. As disclosed by Gura (Science (1997) vol. 278, pp. 1041-42) *in-vitro* cell culture studies are not predictive of *in-vivo* human treatment.

It is noted that there is not a single example in the instant specification, *working or prophetic*, which indicates that the product of the instant disclosure would treat breast adenocarcinoma, colon adenocarcinoma and ovary adenocarcinoma. For example, the data found in the specification is inconclusive to support the breadth of the claimed invention. Taking the examples of pages 11-13 into consideration, it appears that Applicant has found that the *Pistacia lentiscus* oil does have some effect on treating carcinoma cells *in vitro*. However, again, there is no indication that this response can be reasonably extrapolated to cancer treatment or prevention, or any other type of treatment or prevention.

Again, the claim is drawn to specifically treating or preventing cancer. However, Applicant has not demonstrated the effectiveness of *Pistacia lentiscus* oil on cancer. The skilled artisan would not have a reasonable expectation that the response displayed in the instant specification would reasonably extrapolate to treatment of cancer lacking substantial evidence in the specification as well as the prior art pertaining to the efficacy of *Pistacia lentiscus* oil.

The high degree of unpredictability associated with the claimed method underscores the need to provide teachings in the specification that would provide the skilled artisan with specific treatment regimens that achieve a therapeutic benefit; however, the specification does not provide such guidance and fails to provide evidence that *Pistacia lentiscus* oil actually treat cancer. Without such guidance in the specification and the lack of correlative working examples,

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the claims would *require an undue experimentation without a predictable degree of success on the part of the skilled artisan.*

In re Fisher, 427 F.2D 833, 166 USPQ 18 (CCPA 1970), held that “inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some ways on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; **however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112**; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.” (emphasis added).

Summary

No claim is allowed.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner’s supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

Susan D. Coe
2-3-05
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PATENT EXAMINER